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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,973	12/09/2003	Eric R. First	17637 (BOT)	6433

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 12-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10,12-21,23 and 25-27* is/are rejected.

7)☒ Claim(s) *22 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on October 16, 2007 is acknowledged. Claims 1-6, 8-10 and 12-27 are pending. Claims 1, 2, 5, 6, 8, 9, 10, and 12-16 have been amended. Claims 17-27 have been added. Claims 1-6, 8-10, and 12-27 are under consideration.

Rejections Withdrawn

1. In view of Applicant's amendment the rejection of claims 13-16 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter rejection) is withdrawn. Applicant's amendment to remove "the step of administering a therapeutically effective amount of a reconstituted liquid solution of botulinum toxin via syringe to a location of a skin disorder of the patient..." obviates this rejection.

2. In view of Applicant's amendment the rejection of claims 6 and 8-10 under 35 U.S.C. 103(a) as being unpatentable over Kwon (U.S. 2004/0087893 A1) is withdrawn. Applicant's amendment to remove "the step of locally administering between 1 unit and 3000 units of a reconstituted liquid solution of botulinum toxin to a skin disorder of the patient, wherein the skin disorder comprises a disorder selected from the group consisting of warts, corns, calluses, a swelling or scarring of a nerve that connects two

toes, hammertoes and bunions, thereby treating the skin disorder" obviates this rejection.

Rejections Maintained

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The rejection of claims 1-6, 8-10, 12-21 and 25-27 under 35 U.S.C. 102(e) as being anticipated by Kwon (U.S. 2004/0087893 A1), as evidenced by Allergan (pages 1-4, http://www.allergan.com/download/BotoxPI.pdf, accessed on March 22, 2007) in the rejection of claims 1-5, and 12 is maintained for the reasons set forth in the previous office action.

Applicant argues that:

1) The Kwon publication discloses a drug delivery device that administers a drug to the patient in a solid form by piercing the skin with solid perforators comprising the drug, and only after administration, is the drug subsequently released into the skin after the matrix comprising the perforators begin to degrade or dissolve.

2) The Kwon reference does not read on the presently claimed methods because this reference discloses a device that administers a solid form composition comprising a drug and not a liquid solution as presently claimed.

3) It is only after subsequent exposure to bodily fluids or a solvent in a reservoir

is the matrix material degraded or dissolved and the drug subsequently released into the body.

4) There is a definite material difference between administering a drug in a solid form versus a liquid solution. One such material difference is that drugs administered using a SSP device allow for a controlled release of the drug. A liquid is a one time administration that cannot control the release of a drug over time.

5) The issue at the time of administration to the patient is the form of the composition comprising the botulinum toxin type A.

6) Kwon does not read on the presently claimed method because it does not administer a botulinum toxin using an intradermal or subdermal injection or a topical cream or lotion.

Applicant's arguments have been considered, but have not been deemed persuasive.

The claims are drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising the step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder; wherein the solution is administered by intradermal injection or subdermal injection; and wherein the skin disorder comprises a wart, callus, a swelling or scarring of a nerve that connects two toes, or a bunion.

With regard to Points 1 and 2, the method is drawn to a method that comprises the step of administering botulinum toxin to a patient to treat a wart, callus, a swelling or scarring of a nerve that connects two toes, or a bunion. The Kwon reference discloses a method of treating corns, warts, calluses, bunions and keratoses comprising administering a therapeutically effective amount of botulinum toxin. While the Kwon reference discloses the use of a SSP (which uses needles, blades or other perforators), at the point of administration the botulinum toxin is in a solution form, which is indicative of a liquid solution.

With regard to Point 3, the instant claims do not preclude the use of a solid solution that transitions to a liquid since said liquid is effectively "administered to the location of a skin disorder" as required by the instant claims.

With regard to Point 4, as argued in Point 3, the botulinum toxin of the Kwon reference is effectively administered in a liquid state. Moreover, in response to Applicant's argument that there is a definite material difference, it is noted that the features upon which applicant relies (i.e., the liquid is a one time administration that cannot control the release of a drug over time) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Consequently, the Kwon reference anticipates the instantly claimed invention.

With regard to Point 5, contrary to Applicant's argument, the form of the composition comprising botulinum toxin A at the time of effective administration is a

solution. The Kwon reference discloses a method of treating corns, warts, calluses, bunions and keratoses comprising administering a therapeutically effective amount of botulinum toxin. While the Kwon reference discloses the use of a SSP, at the point of administration the botulinum toxin is in a solution form, which is indicative of a liquid solution.

With regard to Point 6, contrary to Applicants argument, Kwon discloses a method of treating corns, warts, calluses, bunions and keratoses comprising administering a therapeutically effective amount of botulinum toxin. While the Kwon reference discloses the use of a SSP (which uses needles, blades or other perforators), at the point of administration the botulinum toxin is in a solution form, which is indicative of a liquid solution. Moreover, Kwon discloses administering the botulinum toxin via a patch (topical). Kwon discloses that a design of an SSP patch includes an array of perforators that is porous and optionally serves as a drug reservoir and the active ingredients are contained in the perforator, which by definition penetrates the surface, makes a hole through or into the skin, thus meeting the limitation of intradermal or transdermal. Kwon discloses that the design is ideal for potent drug delivery, for administering small doses systemically, or for topical applications (see page 5, paragraph 0049).

As previously presented, Kwon discloses a method of administering a safe and effective amount of botulinum toxin for treating lesions or abnormal skin features, such as pimples, corns, warts, calluses, bunions and keratoses (see page 6, paragraph 0077). Moreover, Kwon discloses administering the botulinum toxin via a patch

(topical). Kwon discloses that a design of an SSP patch includes an array of perforators that is porous and optionally serves as a drug reservoir and the active ingredients are contained in the perforator. Kwon discloses that the design is ideal for potent drug delivery, for administering small doses systemically, or for topical applications (see page 5, paragraph 0049).

The instant specification has characterized a therapeutically effective amount as an amount to alleviate a symptom of a skin disorder (see page 21), inherently Kwon has administered a therapeutically amount of botulinum toxin. With regard to claims 8-10, due to the mode of action of botulinum toxin its administration would necessarily reduce a pain and/or inflammation associated with the skin disorder as well as reduce the size of a disorder selected from the group consisting of warts, corns, calluses, a swelling or scarring of a nerve that connects two toes, hammertoes and bunions. Moreover, in view of all disclosed above the method necessarily encompasses intradermal or subdermal injection as well as a topical wherein the composition is a cream or lotion.

New Grounds of Objection and Rejection

Claim Objections

4. Claims 22 and 24 are objected to for depending on rejected based claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 12-16 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Orloff et al. (Surg 1999; 121(4): 410-413).

The claims are drawn to a method for treating a skin disorder in a patient in need thereof, the method comprising a step of administering a therapeutically effective amount of a liquid solution comprising a botulinum toxin to a location of a skin disorder of the patient, wherein the administration of the botulinum toxin reduces at least one symptom of the skin disorder, thereby treating the skin disorder; wherein the solution is administered by intradermal injection or subdermal injection; and wherein the skin disorder comprises a dermatofibroma, a mole, a granuloma, or a keratose.

Orloff et al. disclose a method for treating vocal fold granuloma with botulinum toxin. Orloff et al. disclose that the method comprises injecting botulinum toxin type A into the thyroarytenoid muscle. Orloff et al. disclose that the dosage ranged from 1.25 to 20 U of toxin per injection (see page 410; methods and material). Orloff et al. disclose that vocal fold granulomas are lesions that have labels such as pyogenic granuloma, which reflect the inflammatory and friction-derived origin of these lesions (see page 410, 1st paragraph).

Orloff et al. discloses the method of the instant claims its administration of botulinum toxin would necessarily reduce a pain and/or inflammation associated with the skin disorder as well as reduce the size of a disorder selected from the group

consisting of warts, corns, calluses, a swelling or scarring of a nerve that connects two toes, hammertoes and bunions.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Moreover, Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on October 16, 2007 prompted additional new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a) and MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
10/26/07

ROBERT A. ZEMAN
PRIMARY EXAMINER